K 070924

Attachment V

JUN 2 1 2007

510(k) Summary

1.General Information

Submitter:	AllMed Systems Inc. 9232 Klemetson Drive Pleasanton CA 94588
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Fax	925-399-5984
Contact Person	Peter Allen
Date Prepared	4th April 2007

2. Names

Device Name	FlexGuard Family
Classification Name	Laser Accessory

3. Predicate Device

Cook – Laser Ureteral Catheter

4. Product Description

The FlexGuard is a family of flexible sheaths that are used to protect the working channel of a flexible scope or surgical device from mechanical damage when the laser fiber is introduced into the working channel. The tip of the FlexGuard is allowed to protrude approx 3mm beyond the laser fiber, this assembly is then inserted into the working channel of the scope. The FlexGuard Family is designed to work with a range of laser fibers from 200 micron to 600 micron diameter.

It consists of:

Flexible Sheath
Fiber clamp/Yee piece

Reference Attachment II for photographs detailing and describing the components of the FlexGuard. Reference Appendix VIII for a list of fibers that can be used in conjunction with the FlexGuard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AllMed Systems, Inc.
% Mr. Peter Allen
President
9232 Klemetson Drive
Pleasanton, California 94588

JUN 21 2007

Re: K070924
Trade/Device Name: FlexGuard
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX, FED
Dated: May 4, 2007
Received: May 7, 2007

Dear Mr. Allen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K070924

Device Name: FlexGuard

Indications For Use:

The FlexGuard Family of sheath's are intended for use in surgical procedures using flexible scopes and other approved flexible or rigid fiber optic delivery devices, to protect the working channel from damage when a laser fiber is introduced and also to provide irrigation to the surgical site when used for incision, excision, ablation, vaporization and coagulation of soft tissue with any approved laser with a wavelength from 532nm to 2100nm in medical specialties including: Urology, Gasteroenterology, Thoracic, Head and Neck, Pulmonary, Gynecology, ENT and General Surgery

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070924

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)